

CATARDERCIRAL What Better feels like."

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INTEGRATIVE THERAPEUTICEINC

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 + F: 503.582.0467

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 - F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

JAN 17 2006

January 3, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	2-Week Program to eliminate toxins*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date:

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.

Michael P. Devereux **Chief Operations Officer** 

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INTEGRATIVE THERAPEUTICS INC."

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Tyler Encapsulations + Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

# ENZYMATIC THERAPY\* & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, Wi 54311-8328 P: 920.469.1313 • F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

### № СОЯРОБАТЕО What **Better** feels Uke."

January 3, 2006

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Gentle cleanse and refortify*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:		_	KIT	CULL
	-			

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/3/06

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Whether this is your first cleanse, or you	Proprietary Fiber Blend -psyllium
	realized the need to keep your intestinal	(Plantago ovata) husk, oat (Avena sativa)
	system healthy years ago, you can count on	bran, guar gum (Cyamopsis
	the Enzymatic Therapy family of Internal	tetragonoloba) seed extract, pectin (from
	Cleansing Systems for a safe and natural	citrus fruit), and marshmallow (Althaea
	cleansing experiencewith fiber!*	officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:	FLECILE
	Robert Doster Senior Vice President of Scientific Affairs
Date:	1/3/06

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Sincerely,



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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>™</sup>	Enzymatic Therapy's Fiber Fusion is a combination of all-natural fibers and herbs that safely absorbs and eliminates toxins and improves colon function.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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Ву:	Total William
Title:	Robert Doster Senior Vice President of Scientific Affairs
Date:	1/10/06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Our True Dispersion delivery system ensures the fiber is completely released and dispersed throughout the colon for thorough cleansing.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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Ву:	KLICILL
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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Dietary Supplement safely absorbs and eliminates toxins and improves colon function.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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Ву:	KIRCILL
	Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/06

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Sincerely



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Our patent-pending True Dispersion technology ensures the fiber is completely released and dispersed throughout the colon for thorough cleansing.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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By:		

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/86

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Sincerely, Michael P. Jevamp



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PRODUCT NAME	STATEMENTS 1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion™	Detoxification helps eliminate bodily toxins, strengthens the immune system and improves health.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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Ву:	KINCILL
	Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



INTEGRATIVE THERAPEUTICS INC. NF Formulas & PhytoPharmica
Tyler Encapsulations & Vitaline Formulas

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Safely and naturally restores your body's own natural balance in just fourteen days.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Whole Body Cleanse and Simple Cleanse from Enzymatic Therapy handle the environmental toxins you take in from the environment (like pollutants) as well as toxins that you make yourself (like free radicals), without depleting your body's store of beneficial nutrients.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(SITO WHICH THE CLAIM REFERS
Fiber Fusion <sup>™</sup>	Both Whole Body Cleanse and Simple Cleanse use natural herbs and plants to work in harmony with the body's built-in purification system.* You get healthy, comfortable internal cleansing and thorough detoxification without depleting beneficial nutrients.* So, choose the Cleanse that's right for you and enjoy your journey to Rejuvenation.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaca officinalis) root extract

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mus.	Robert Doster
	Senior Vice President of Scientific Affairs
Date:	1/10/06

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Sincerely,

Michael P. Devereux

Chief Operations Officer



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Fiber Fusion™	Digestive, Liver and Lymph Cleanse.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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By: KLYCUL

Robert Doster

Title: Senior Vice President of Scientific Affairs

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Date: 1/10/06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion™	Finally, a high-strength, gentle Whole Body Cleanse that enhances your body's own natural internal cleansing process for thorough detoxification.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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By:		RIS	61	lt
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Robert Doster
Title: Senior Vice President of Scientific Affairs

Date: 1/10/0%

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Operations Officer

Eiber Ension 61e



INTEGRATIVE THERAPEUTICS INC."

NF Formulas \* PhytoPharmica

Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 A F: 503.582.0467

# ENZYMATIC THERAPY' & PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

What Better feels like."
January 10, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion™	Simple 2-week Whole Body Program to cleanse, detoxify and refortify!*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KIRCHE

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/010

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



INTEGRATIVE THERAPEUTICS INC.

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Wilsonville, OR 97070
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What Better feels like.™
January 10, 2006

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	The Whole Body Cleanse supports detoxification of the intestines, liver, gall bladder, circulatory and lymphatic systems.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:			 *	4	¥	C	U	1	

Robert Doster

Title: Senior Vice President of Scientific Affairs

Never P

Date: 1/10/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely



### INTEGRATIVE THERAPEUTICS INC.

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Tyler Encapsulations \* Vitaline Formulas

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# ENZYMATIC THERAPY & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

### ENZYMATIC THERAPY

What Better feels like."

January 10, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

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Label Claims/Disclaimers

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion™	Patent-pending True Dispersion Technology gives you fiber that goes to work instantly and cleans all the way down.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICILL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



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#### ENZYMATIC THERAPY & PHYTOPHARMICA\*

### ENZYMATIC THERAPY

What Better feels like."

January 11, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>™</sup>	Safe, Natural, Complete*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:	KIRCHT	•

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

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Sincerely,

Michael P. Devereux



INTEGRATIVE THERAPEUTICS INC."

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Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 & F: 503.582.0467

#### ENZYMATIC THERAPY & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 \* F: 888.570.6460 (Enzymatic) P: 920.469.9099 \* F: 920.469.4418 (Phyto)

What Better feels like.™ January 11, 2006

REDRPERATED

Office of Nutritional Products, Labeling & Dictary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	More mucilage content than flax fiber - cleanses more toxins.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: RIPCILE

Robert Döster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely



### •

INTEGRATIVE THERAPEUTICS INC."

NF Formulas • PhytoPharmica

Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

#### ENZYMATIC THERAPY & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

Wbat Better feels like."

January 11, 2006

ENZYMATIC THERADY

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Better health can be achieved through Enzymatic Therapy's Whole Body approach to detoxification and rebuilding.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

ILL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely



#### INTEGRATIVE THERAPEUTICS INC."

NF Formulas \* PhytoPharmica
Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 & F: 503.582.0467

### ENZYMATIC THERAPY

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 - F: 888.570.6460 (Enzymatic) P: 920.469.9099 + F: 920.469.4418 (Phyto)

### ENZYMATIC THERAPY

What Better feels like."

January 11, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Targeted Intestinal Cleanse.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Kliffilt

Robert Doster

Title: Senior Vice President of Scientific Affairs

hal P. Nevemp

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely



INTEGRATIVE THERAPEUTICS INC."

NF Formulas \* PhytoPharmica

Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 & F: 503.582.0467

### ENZYMATIC THERAPY' & PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

What Better feels like."

January 11, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Labe

Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Gentle, no stimulant laxative safely cleanses and strengthens the body's natural detoxification process.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	feld little
-	Robert Doster
Title:	Senior Vice President of Scientific Affairs
Date:	1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.



#### INTEGRATIVE THERAPEUTICS INC.

NF Formulas « PhytoPharmica Tyler Encapsulations » Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

#### ENZYMATIC THERAPY & PHYTOPHARMICA\*

### ENZYMATIC THERAPY

What Better feels like."

January 11, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
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PRODUCT NAME.	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion™	Enzymatic Therapy's Fiber Fusion features True Dispersion Technology, a system that thoroughly disperses and completely releases these fibers throughout the entire colon.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KURUŁ

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.



INCORPORATED

Tyler Encapsulations « Vitaline Formulas 9755 SW Commerce Circle, Suite B2

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467

INTEGRATIVE THERAPEUTICS INC."

NF Formulas \* PhytoPharmica

### ENZYMATIC THERAPY' & PHYTOPHARMICA'

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Contains a soothing herbal blend and promotes healthy, comfortable bowel cleansing and effective detoxification.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:	,	kricht
-	 *	,

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



NF Formulas « PhytoPharmica

Tyler Encapsulations « Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>™</sup>	The Fiber Fusion safely absorbs and eliminates toxins and improves colon function.* It binds the toxins loosened by the Laxative with highly effective all-natural fibers and herbs, including: Oat bran - the most soluble fiber of any grain.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	Twint water
	Robert Doster Senior Vice President of Scientific Affairs
Date:	1/11/06

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Sincerely,



#### INTEGRATIVE THERAPEUTICS INC.

NF Formulas \* PhytoPharmica
Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 • F: 503.582.0467

# ENZYMATIC THERAPY' & PHYTOPHARMICA'

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### ENZYMATIC THERAPY

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January 11, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

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PRODUCT NAME	STATEMENTS,	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	The Fiber Fusion safely absorbs and	Proprietary Fiber Blend -psyllium (Plantago
	eliminates toxins and improves colon	ovata) husk, oat (Avena sativa) bran, guar gum
	function.* It binds the toxins loosened	(Cyamopsis tetragonoloba) seed extract, pectin
	by the Laxative with highly effective	(from citrus fruit), and marshmallow (Althaea
	all-natural fibers and herbs, including:	officinalis) root extract
	Pectin from citrus fruit - provides fiber	
	and support immune health, too.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KIPCUT

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

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Sincerely,



#### INTEGRATIVE THERAPEUTICS INC.

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# ENZYMATIC THERAPY

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### ENZYMATIC THERAPY

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	The Fiber Fusion safely absorbs and eliminates toxins and improves colon function.* It binds the toxins loosened by the Laxative with highly effective all-natural fibers and herbs, including:  Psyllium husk (has more reabsorption ability than any other bowel-regulating fiber).*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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By: KLICILL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



INCORPGRATED

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070 P: 503.582.8386 & F: 503.582.0467

INTEGRATIVE THERAPEUTICS INC." NF Formulas # PhytoPharmica Tyler Encapsulations & Vitaline Formulas

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 • F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

What Better feels like." January 11, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	To keep up your vibrant new state and continue to restore and rebuild your system follow the maintenance program below.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:	RUPCILL
	Robert Doster
Title:	Senior Vice President of Scientific Affair

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.



#### INTEGRATIVE THERAPEUTICS INC."

NF Formulas \* PhytoPharmica
Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 & F: 503.582.0467

# ENZYMATIC THERAPY & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

### ENZYMATIC THERAPY

NOORPORATED

What Better feels like."

January 11, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAYM REFERS
Fiber Fusion™	The key to superior digestive health is gentle detoxification with The Whole Body Cleanse.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

	RUPPLE
Ву:	- Jana water

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

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Sincerely.



#### INTEGRATIVE THERAPEUTICS INC."

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January 11, 2006

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Simple Cleanse supplies a targeted intestinal cleanse to get your system back on track.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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By: KLICILE

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Nevemp

Sincerely.



INCORPORATED

INTEGRATIVE THERAPEUTICS INC.\*

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### What Better feels like™

January 11, 2006

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion™	Features True Dispersion Fiber plus natural herbs and plants that work in harmony with the body's own built-in purification systems.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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Bv:	_	1	U	C	llt
-	Robert Dos	ster			

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

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Sincerely,



NF Formulas \* PhytoPharmica
Tyler Encapsulations \* Vitaline Formulas

EGRATIVE THERAPEUTICS INC."

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 • F: 503.582.0467

# ENZYMATIC THERAPY® & PHYTOPHARMICA®

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PRODUCT NAME	STATEMENTS .	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Psyllium supports cardiovascular, endocrine, and immune health, additional health benefits than other detoxification fibers often lack.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	KINCILL
	Daland Danden

Robert Doster

Title: Senior Vice President of Scientific Affairs

P. Nevemp

Date: 1/11/06

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Sincerely.



INTEGRATIVE THERAPEUTICS INC. NF Formulas \* PhytoPharmica Tyler Encapsulations \* Vitaline Formulas

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INSORPORATED What Better feels like™ January 11, 2006

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Intestinal flora can also ferment psyllium into short-chain fatty acids (SCFA), supporting intestinal health and repair.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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Ву:				KIRCUL
-	 -	4	 *	

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.



#### INTEGRATIVE THERAPEUTICS INC."

NF Formulas + PhytoPharmica
Tyler Encapsulations + Vitaline Formulas

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### ENZYMATIC THERAPY

INCORPORATED

What Better feels like."

January 11, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Fiber Fusion contains a proprietary blend of fibers with clinically validated effectiveness.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: RUCUL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux



January 11, 2006

INCORFORATED

What Better feels like."

INTEGRATIVE THERAPEUTICS INC."

NF Formulas 
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#### ENZYMATIC THERAPY' & PHYTOPHARMICA'

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Psyllium husk is a rich source of	Psyllium (Plantago ovata) husk
	concentrated soluble fiber that supports	
	healthy intestinal function.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

	KLICILE
By:	- June water

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



#### INTEGRATIVE THERAPEUTICS INC."

NF Formulas PhytoPharmica
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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	In studies, psyllium husk has been shown to	Psyllium (Plantage ovata) husk
	absorb up to fourteen times its weight in	4
	water and has more reabsorption ability than	
	any other bowel-supporting fiber.*	· ·

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICUL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

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Jeven

Sincerely



#### INTEGRATIVE THERAPEUTICS INC."

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Wilsonville, OR 97070

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### ENZYMATIC THERADY NCGRPDRATED

What Better feels like."

January 11, 2006

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PRODUCT NAME	STATEMENTS LEADING	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Fiber Fusion™	The most soluble fiber of any grain, oat bran	Oat (Avena sativa) bran
	forms a bulky gel in the intestine, which	
	regulates the flow of excretory matter	
	through the digestive tract.*	

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By:	•	KI	20	UL
-				

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

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INTEGRATIVE THERAPEUTICS INC."

NF Formulas + PhytoPharmica

Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467

# ENZYMATIC THERAPY\* & PHYTOPHARMICA\*

what Better feels like."

January 11, 2006

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Research has demonstrated that oat bran supports healthy bile acid synthesis, prevents free radical damage as an antioxidant, and supports healthy low-density lipoprotein levels that are already within normal levels.*	Oat (Avena sativa) bran

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KILLULL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/1/06

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Sincerely,

Michael P. Devereux



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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Research has demonstrated that guar gum supports intestinal health and elimination of excretory matter through the colon.* This natural fiber has the additional benefit of mucilaginous properties, supporting intestinal wall health and facilitating the ease of elimination.*	Guar gum (Cyamopsis tetragonoloba) seed extract

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Ву:	fleelt
·	Robert Doster Senior Vice President of Scientific Affairs
Date:	1/4/010

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Pectin from citrus fruit is a soluble fiber that has been studied for its support of immune health.* This natural fiber has the additional benefit of mucilaginous properties, supporting intestinal wall health and facilitating the ease of elimination.*	Pectin (from citrus fruit)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Bv:	KIRCIL	£

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/0/6

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion <sup>TM</sup>	Mashmallow root has been studied for its support of colon mucosa.* These natural fibers have the additional benefit of mucilaginous properties, supporting intestinal wall health and facilitating the ease of elimination.*	Marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	KLICILL
Title:	Robert Doster Senior Vice President of Scientific Affairs
Date:	1/11/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



INTEGRATIVE THERAPEUTICS INC."

NF Formulas \* PhytoPharmica

Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503,582.8386 & F: 503.582.0467

#### NZYMATIC THERAPY & Phytopharmica\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

What Better feels like."

January 12, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REPERS
Fiber Fusion™	Research has demonstrated that oat bran supports healthy bile acid synthesis, prevents free radical damage as an antioxidant, and supports healthy low-density lipoprotein levels that are already within normal levels.*	Oat (Avena sativa) bran

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Bv:	KIRCILL
~ , .	

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/010

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE GLAIM REFERS
Fiber Fusion™	As part of a gentle and effective detoxification program, Fiber Fusion aids in the binding and excretion of harmful toxins.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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	KLYCIL	Ł
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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	The blend of all-natural fiber sources in Fiber Fusion supports healthy intestinal function, promotes healthy bowel elimination, supports healthy bile synthesis, healthy serum cholesterol levels that are already within normal limits, and healthy immune function.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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Title:	Robert Doster Senior Vice President of Scientific Affairs
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Sincerely,

Michael P. Devereux



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PRODUCT NAME	STATEMENTS	INGREDIENT(SITO WHICH THE CLAIM REFERS
Fiber Fusion™	With Enzymatic Therapy's Simple Cleanse there is no depletion of vital vitamins, minerals, and enzymes that can leave users feeling drained and fatigued.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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By:	KIRCHE
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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/06

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PRODUCT NAME	STATEMENTS.	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Fiber Fusion can help resolve occasional constipation.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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By:	Kild Little
Title:	Robert Doster Senior Vice President of Scientific Affairs
Date:	1/12/06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™	Fiber has the key role of safely absorbing Fiber Fusion and eliminating toxins. The toxins actually bind to the fiber and are excreted from your body. Without this all important inclusion in the cleansing process, toxins can go right back into your blood stream.*	Proprietary Fiber Blend -psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), and marshmallow (Althaea officinalis) root extract

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Robert Doster

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